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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,234	04/26/2001	Kiyoshi Nakayama	P20938	7436

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1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,234

Applicant(s)

NAKAYAMA ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 22 and 24-33 are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 5 and 28-33 are allowed.
- 6) ☒ Claim(s) 4, 6-18, 20, 22, 24-27 are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This office action is in response to the amendment filed on December 16, 2004.

Claims 1-18, 20, 22 and 24-33 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

Claims 4, 6, 7-18, 20, 22 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic treatment of a microbial infection due to *Pseudomonas aeruginosa*, does not reasonably provide enablement for therapeutic and/or preventive treatment of microbial infections due to other microorganisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments and the amendments to claims 4, 6 and 20 have been fully considered but they were not deemed to be persuasive. Applicant first relies on the amendment to the claims wherein the recitation "a microbial infection" has been replaced with "infection by microorganisms selected from *Pseudomonas aeruginosa* and bacteria having a genetically homologous drug efflux pump", to overcome the rejection. However, the recitation "bacteria

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having a genetically homologous drug efflux pump' has not been fully supported in the specification. The specification does not provide what types of 'bacteria' are intended by the above recitation, nor provides examples of such bacteria. Applicant submits that 'support is found generally in the specification, including in page 2, lines 12-14'. However, the above terminology was not found anywhere in the specification and page 2, lines 12-14 have the following disclosure (portion of specification provided for convenience):

The drug efflux pumps of *Pseudomonas aeruginosa* excrete various drugs including β -lactams, tetracyclines, chloramphenicols, and quinolones, to which the drug resistance of *Pseudomonas aeruginosa* is attributable.

The specification does not provide what types of bacteria or microorganism are intended to be included in the above recitation. In the specification at page 2, lines 7-11, there is a discussion of 'homological drug efflux pumps derived from *Pseudomonas aeruginosa*' the cited references therein have been fully considered, however, they do not provide sufficient disclosure regarding the types of microorganisms included in the recitation. For example, Kohler (1997) suggests 'three types of mutants which display multiple drug-resistant (MDR) phenotype for *P. aeruginosa*' and further provides that 'there is a major difference between the three systems' (see page 351) and 'whether the expression is controlled by an analogous regulatory mechanism in *P. aeruginosa* remains to be determined'. Applicant has neither provided sufficient supporting disclosure for the amended claims nor indicated what types of bacteria or microorganisms are intended by the recitation and therefore, it is maintained that the specification does not enable

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any person skilled in the art to which it pertains to use the invention commensurate in scope with the claims.

Applicant next relies on the amendment to claims 4, 6 and 20 wherein the “preventive” language has been removed, to overcome the rejection. However, composition claims and the method of use claims were rejected in the previous office action and it was clearly set forth that the claims “while being enabling for therapeutic treatment of a microbial infection due to *Pseudomonas aeruginosa*, does not reasonably provide enablement for therapeutic and/or preventive treatment of microbial infections due to other organisms”. Claims 13-18, 26 and 27 continue to recite “A method for **preventive treatment**...” which is not enabled for the reasons provided in the previous office action. Applicant did not provide any arguments and relied on the amendment to claims 4, 6 and 20 wherein the “preventive” language has been removed. This is not sufficient for the reasons provided previously.

The following rejections are necessitated by the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6, 7-18, 20, 22 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as filed does not provide support and written description for the recitation "bacteria having a genetically homologous drug efflux pump", which was added to the claims in the recent amendment. Applicant indicated that the recitation finds support at page 2, lines 12-14, however, this was not found to be the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 7-18, 20, 22 and 24-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the above claims it is not clear what is intended by the recitation "bacteria having a genetically homologous drug efflux pump". The specification does not provide any explanation or representative examples.

Allowable Subject Matter

Claims 1, 2, 3, 5 and 28-33 are allowed. The references of record do not teach or fairly suggest the claimed compounds.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

March 3, 2005